



✓ Site: Atlanta, GA

# FDAMA STAKEHOLDER MEETING

APRIL 28, 1999

## Talking with Stakeholders About FDA Modernization

\*\*Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 only)

Title (required) ☒ Dr. ☐ Mr. ☐ Mrs. ☐ Ms. First Name (required) Steven Last Name (required) Johnson  
Organization Grady Health System

Stakeholder Group ✓ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☒ Health Professional ☐ Industry ☐ Association ☐ Other

Center ✓ the center/product area your comments address

☐ Center for Biologics ☐ Center for Drug Evaluation and Research  
☐ Center for Devices and Radiological Health ☐ Center for Food Safety and Applied Nutrition  
☐ Center for Veterinary Medicine ☐ Office of Regulatory Affairs  
☒ FDA General

### Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

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- ☐ 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
  - ☒ 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
  - ☒ 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
  - ☐ 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
  - ☐ 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
  - ☐ 6. Additional Comments on FDA Modernization Efforts.

### YOUR COMMENT/QUESTION

What actions is FDA considering with regard to Patient Package Inserts (from industry - the 5-10 selected by FDA/year) to meet the needs of low-literacy patients? Dr. The average reading level of our patient population is 4<sup>th</sup> grade. The Estrogen PPI's appear to be written above the 8<sup>th</sup> grade level.

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